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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,554	11/10/1999	ARISTOS ARISTIDOU	0933-148P	6884

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/423,554	ARISTIDOU ET AL.	
	Examiner	Art Unit	
	Malgorzata A. Walicka	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on Nov. 19.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 11-16, 23, 24, 27, 31, 32 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17-22, 25, 26, 28, -30, 33, and 38-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5</u> . | 6) <input type="checkbox"/> Other: _____ |

The examiner acknowledges the amendment filed on November 19, 2001, paper No. 12. Amendments to the specification and claims have been entered. The new claim number 39 was added. Claims 11-16, 23, 24, 27, 31, 32, 34-37 are withdrawn from consideration as nonelected, paper No. 9. Claims 1-10, 17-22, 25, 26, 28-30, 33 and 38-39 are the subject of this Office action.

Detailed Office Action

1. *Objections*

1.1. *Specification*

The objection to the specification for the usage of the phrase: "recombinant molecule encoding or otherwise causing the expression of"; for example page 9, line 32. Has not been withdrawn. The change of the language to "recombinant molecule encoding **and** causing the expression of" would cause withdrawal of this objection. *ok*

The objection to the title of Table 3 has been withdrawn in the light of the amendment.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicant may become aware.

1.2. *Drawings*

This application has been filed with informal drawings, which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

2. *Rejections*

2.1. *35 USC 112, second paragraph*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 1-10, 17- 22, 28-30, 33 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 1, 17 and 21 have been rejected for several phrases making the claims indefinite or confusing:

Rejection still holds as to the phrase "at least one recombinant DNA molecule encoding or causing the expression of at least one enzyme." This phrase renders the claim indefinite. The change of the language to "recombinant molecule encoding **and** causing the expression of" would cause withdrawal of this objection.

Dependent claims 2-10, 18-20, 22, 28-30, 33 and 38 are including into rejection because they do not correct deficiency of the claim from which they depend.

The term "required metabolic capacity" in claim 7 is a relative term which renders the claim indefinite. The term "required metabolic capacity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

ok
now

2.1.1. Rejection withdrawals

The rejection based on the use of the phrase " two pyrimidine nucleotide-linked dehydrogenase reactions with **different** specificities for the NAD/NADH and NADP/NADPH coenzyme couples" has been withdrawn in the light of Applicants' arguments.

The rejection concerning "so facilitates the transfer of electrons." Has been withdrawn in the light of Applicants arguments.

The rejection concerning the term "useful product" has been withdrawn in the light of the Applicants arguments.

Rejection of claim Claim 2, 6 and 28 because of use of the terms:

"raw material",
"biotechnological process"

has been withdrawn in the light of Applicants arguments.

2.2. 35 USC 112, first paragraph

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The rejection of Claims 1, 17 and 18 under 35 USC 112, first paragraph has not been withdrawn, because the applicants arguments were found unpersuasive.

In addition a new rejection of claim 1 and dependent claims is proper in the light of the amendment of Nov. 19, 2001.

Claims 1 and 1-10, 17- 22, 28-30, 33 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for production ethanol, does not reasonably provide enablement for any industrial product being more reduced than pyruvate. Claims are so broad as to encompass any compound that is more reduced than pyruvate. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the large number of chemical compounds broadly encompassed by the claims. The disclosure is limited to ethanol.

While the methods of microorganism engineering are well developed and skills of that in the art highly developed, it is not routine in the art to engineer all transformant that that have the characteristic described by claim 1 and will produce all compound that are more reduced than pyruvate. The specification does not support the broad scope of the claim which encompass all chemical compounds more reduced than pyruvate that are industrially produced by microorganisms that are transformed with at least one recombinant DNA molecule encoding or causing expression of a gene of at least one enzyme that causes the functional coupling of the oxidation and reduction of substrates by the two pyridine nucleotide-linked dehydrogenase reactions that share a common substrate and have different specificities for NAD/NADH and NADP/NADPH coenzyme couples. The specification provides insufficient guidance as to which of the large number of compounds is to be produced at the industrial scale.

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Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claim broadly including industrial production of any chemical compound that is reduced more than pyruvate. The scope of the claim must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination which of extremely large number of chemical compounds to be produced at the industrial scale is unlikely to be successful. Thus the experimentation left to those skilled in the art is unnecessarily and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Allowable claims 25 and 26 are still rejected because Applicants have not provided the certification that the biologic deposit meets the criteria set forth in 37 CFR 1.801-1.809, as required in the previous Office action, paper No. 10.

2.3. 35 USC, section 102

Rejection of claim 1 under 35 U.S.C. 102(b) has been withdrawn in the light of Applicants' arguments.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent examiner


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